

REMARKS / ARGUMENT

Status of Claims

Claim 1 is amended.

Claim 2 is original.

Claims 3-17 were previously presented.

Claims 18-20 are withdrawn from consideration.

As such, claims 1-17 are pending in this application.

Applicants hereby request further examination and reconsideration of the presently claimed application.

Claim Amendment

Claim 1 has been amended to read:

A transdermal spray formulation comprising:

- a) a pharmaceutically active agent;
- b) 0.1% to about 5.0% by weight VP/VA copolymer;
- c) at least 60% by weight of a non-aqueous solvent; and
- d) optionally a penetration enhancer, which, if present, is present in an amount of 0.01% to 5.0% by weight of the composition.

See supra claim 1 (emphasis added to indicate amending language).

Support for the amending language is found in the specification. *See* Application at ¶ [0028] (“[T]he VP/VA copolymer may be present in an amount between about 0.1% by weight to about 5% by weight of the formulation.”).

Rejections under 35 USC § 102(b)

Claims 1-4, 6-9, and 11-17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by WO 00/45795 to Wain *et al.* (hereinafter “Wain”). Claims 2-17 depend upon Claim 1. “A claim is anticipated only if each and every element **as set forth in the claim** is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). See MPEP § 2131. Applicants respectfully submit that Wain does not anticipate claims 1-4, 6-9, and 11-17 because Wain does not describe each and every element as set forth in independent claim 1. See *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d at 1053.

Wain fails to anticipate claims 1-4, 6-9, and 11-17 because Wain fails to teach a transdermal spray formulation comprising both “0.1% to about 5.0% by weight VP/VA copolymer” and “at least 60% by weight of non-aqueous solvent.” See *supra*, claim 1. Claim 1 reads:

A transdermal spray formulation comprising:

- a) a pharmaceutically active agent;
- b) **0.1% to about 5.0% by weight VP/VA copolymer;**
- c) **at least 60% by weight of a non-aqueous solvent;** and
- d) optionally a penetration enhancer, which, if present, is present in an amount of 0.01% to 5.0% by weight of the composition.

See *supra* (emphasis added).

As shown above, claim 1 recites “0.1% to about 5.0% VP/VA copolymer” and “at least 60% by weight non-aqueous solvent.” In contrast, Wain does not disclose a transdermal spray formulation where the VP/VA copolymer occurs in a range of from 0.1% to about 5.0% **and** the non-aqueous solvent is at least 60% by weight.

As held by the Court of Appeals for the Federal Circuit, it is not sufficient that each element be found somewhere in the reference, the elements must be “arranged as in the claim.”

See *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ 481, 485 (Fed. Cir 1984). While some of *Wain*'s embodiments comprise a non-aqueous solvent in a percentage of greater than 60%, see *Wain* at 11-16; and other *Wain* embodiments comprise film-forming polymers in as little as 5%, see *id.*; *Wain* teaches no single embodiment, nor does it even suggest an embodiment, comprising both "0.1% to about 5.0% by weight VP/VA copolymer" and "at least 60% by weight of a non-aqueous solvent." As held by the Federal Circuit, the elements must be "arranged as in the claim." See *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 221 USPQ at 485.

Because *Wain* fails to "arrange" the elements "as in the claim," *Wain* cannot anticipate claim 1. See *id.* Applicants respectfully submit that claim 1 is presented in allowable condition. Further, because claims 2-4, 6-9, and 11-17 depend from claim 1, claims 2-4, 6-9, and 11-17 are also presented in allowable condition.

Rejections under 35 USC § 103(a)

Claims 1-17 also stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Wain* in view of Mariana Foldvari, *Non-invasive administration of drugs through the skin: challenges in delivery system design*, CHEMICAL ENGINEERING (December 12, 2000) (hereinafter "*Foldvari*"). Applicants respectfully submit that the combination of *Wain* and *Foldvari* does not render obvious claims 1-17 because the Office Action does not clearly articulate how said combination can be construed as containing all of the elements of independent claim 1 to which claims 2-17 depend. As noted by the United States Supreme Court in *Graham v. John Deere Co. of Kansas City*, an obviousness determination begins with a finding that **"the prior art as a whole in one form or another contains all" of the elements of the claimed invention**. See *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 22 (U.S. 1966). As explained in the previous section regarding

rejections under 35 U.S.C. § 102, *Wain* does not disclose all of the elements of the instant invention, and the Office Action does not cite *Foldvari* as to overcome the shortcomings of *Wain*. Furthermore, the MPEP provides:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit.

See MPEP § 2143. Because the Office Action does not “clearly articulate” nor “explicitly support” its obviousness rejection under 35 U.S.C. § 103(a), the Office Action does not establish a *prima facie* case of obviousness as to claims 1-17. As such, claims 1-17 should be allowed as they are not obvious in light of the cited prior art.

CONCLUSION

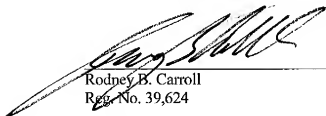
Consideration of the foregoing amendments and remarks, reconsideration of the application, and withdrawal of the rejections and objections is respectfully requested by the Applicants. No new matter is introduced by way of the amendment. It is believed that each ground of rejection raised in the Office Action dated April 15, 2008 has been fully addressed. If any fee is due as a result of the filing of this paper, please appropriately charge such fee to Deposit Account Number 50-1515 of Conley Rose, P.C., Texas. If a petition for extension of time is necessary in order for this paper to be deemed timely filed, please consider this a petition therefore.

If a telephone conference would facilitate the resolution of any issue or expedite the prosecution of the application, the Examiner is invited to contact the undersigned at the telephone number given below.

Respectfully submitted,

Date: _____

9-24-08



Rodney B. Carroll
Reg. No. 39,624

ATTORNEY FOR APPLICANTS

CONLEY ROSE, P.C.
5601 Granite Parkway, Suite 750
Plano, Texas 75024
Tel: (972) 731-2288
Fax: (972) 731-2289